

PATENT
Attorney Docket No. EXT-048



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Shuber
 SERIAL NO.: 09/755,004 GROUP NO.: 1637
 FILING DATE: January 5, 2001 EXAMINER: S. Chunduru
 TITLE: Methods for Detecting, Grading or Monitoring an H. pylori Infection

Commissioner for Patents
Washington, D.C. 20231

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

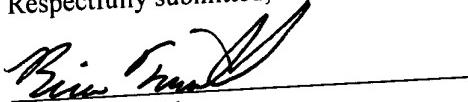
In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- (2) after the period defined in (1) but before the mailing date of a **final action or a notice of allowance** under 37 C.F.R. 1.311, and
 - the requisite Statement is below, **OR**
 - the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- (3) after the mailing date of a **final action or notice of allowance** but before the payment of the **issue fee**, **AND**

- the requisite Statement is below, AND
- the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Respectfully submitted,



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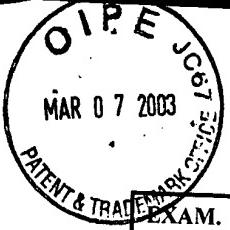


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FORM PTO - 1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: EXT-048 APPLICANT(S): Shuber SERIAL NO.: 09/755,004 FILING DATE: January 5, 2001
OTHER ART, JOURNAL ARTICLES, ETC.		
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
C15	Bélanger et al., "Rapid Detection of <i>Clostridium difficile</i> in Feces by Real-Time PCR," <i>J. Clin. Microbiol.</i> , <u>41</u> (2): 730-734 (Feb. 2003).	
C16	Bickley et al., "Evaluation of the polymerase chain reaction for detecting the urease C gene of <i>Helicobacter pylori</i> in gastric biopsy samples and dental plaque," <i>J. Med. Microbiol.</i> , <u>39</u> (5): 338-344 (1993).	
C17	Bravos et al., "Accurate Diagnosis of <i>Helicobacter pylori</i> ," <i>Gastroenterology Clinics of North America</i> , <u>29</u> (4): 925-929 (Dec. 2000).	
C18	Johnston et al., "Evaluation of Three Commercial Assays for Detection of <i>Giardia</i> and <i>Cryptosporidium</i> Organisms in Fecal Specimens," <i>J. Clin. Microbiol.</i> , <u>41</u> (2): 623-626 (Feb. 2003).	
C19	Kawamata et al., "Nested-Polymerase Chain Reaction for the Detection of <i>Helicobacter pylori</i> Infection with Novel Primers Designed by Sequence Analysis of Urease A Gene in Clinically Isolated Bacterial Strains," <i>Biochem. And Biophys. Research Comm.</i> , <u>219</u> (1): 266-272 (Feb. 1996).	
C20	Mapstone et al., "Identification of <i>Helicobacter pylori</i> DNA in the mouths and stomachs of patients with gastritis using PCR," <i>J. Clin. Pathol.</i> , <u>46</u> (6): 540-543 (Jun. 1993).	
C21	Monteiro, et al., "Complex Polysaccharides as PCR Inhibitors in Feces: <i>Helicobacter pylori</i> Model," <i>J. Clin. Microbiol.</i> , <u>35</u> (4): 995-998 (Apr. 1997).	
C22	Nagashima et al., "Application of New Primer-Enzyme Combinations to Terminal Restriction Fragment Length Polymorphism Profiling of Bacterial Populations in Human Feces," <i>Applied and Environ. Microbiol.</i> , <u>69</u> (2): 1251-1262 (Feb. 2003).	
C23	Osaki, et al., "Detection of <i>Helicobacter pylori</i> in Fecal Samples of Gnotobiotic Mice Infected with <i>H. pylori</i> by an Immunomagnetic-Bead Separation Technique," <i>J. Clin. Microbiol.</i> , <u>36</u> (1): 321-323 (Jan. 1998).	
C24	Shuber et al., "Accurate, Noninvasive Detection of <i>Helicobacter pylori</i> DNA from Stool Samples: Potential Usefulness for Monitoring Treatment," <i>J. Clin. Microbiol.</i> , <u>40</u> (1): 262-264 (Jan. 2002).	
C25	Song et al., " <i>Helicobacter pylori</i> in Dental Plaque: A Comparison of Different PCR Primer Sets," <i>Digestive Dis. and Sci.</i> , <u>44</u> (3): 479-484 (Mar. 1999).	
C26	Uribe et al., "Sensitive Detection of <i>Helicobacter pylori</i> in Gastric Aspirates by Polymerase Chain Reaction," <i>The Journal of the Japanese Association for Infectious Diseases</i> , <u>72</u> (2): 114-122 (Feb. 1998).	
C27	Watanabe, et al., "Detection of <i>Helicobacter pylori</i> Gene by Means of Immunomagnetic Separation-Based Polymerase Chain Reaction in Feces," <i>Scandinavian Journal of Gastroenterology</i> , <u>33</u> (11): 1140-1143 (1998).	
C28	Weiss et al., "Comparison of PCR and Other Diagnostic Techniques for Detection of <i>Helicobacter pylori</i> Infection in Dyspeptic Patients," <i>J. Clin. Microbiol.</i> , <u>32</u> (7): 1663-1668 (Jul. 1994).	
EXAMINER		DATE CONSIDERED

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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C29	Westblom, et al., "Diagnosis of <i>Helicobacter pylori</i> Infection by means of a Polymerase Chain Reaction Assay for Gastric Juice Aspirates," <u>Clin. Infectious Dis.</u> , <u>16</u> (3): 367-371 (Mar. 1993).
	C30	Yoshida et al., "Use of a Gastric Juice-Based PCR Assay To Detect <i>Helicobacter pylori</i> Infection in Culture-Negative Patients," <u>J. Clin. Microbiol.</u> , <u>36</u> (1): 317-320 (Jan. 1998).
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